ANALYTICAL MODELS FOR PREDICTING MECHANICAL PROPERTIES OF SELF-EXPANDABLE METAL STENTS WITH COVER MEMBRANE

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Abstract- **Various mechanical characteristics of stents were analyzed and mathematical models were developed in order to predict expansive pressure of stents. Given the geometry and material properties of a stent, one can utilize these models to predict its expansive pressure properties. Then, these models were verified with the test results derived from some prototype and commercially available stents. The models allow for the characterization of mechanical properties of stents and may be instrumental in developing clinically efficacious stents.**
***Keywords* – Self-expandable metal stent, radial expansive pressure, analytic model**

I. INTRODUCTION

Successful stenting is crucial for maintaining the patency of the organs with luminal obstruction. Three types of stents are commonly used: bare stent (wire only), coated stent (polymer coating on wire), and covered stent (polymer membrane on its peripheral surface). The clinical applicability of these stents largely depends on thorough understanding of their mechanical properties, one of which is radial expansive pressure. In the present study, we propose the mathematical models by which one can predict radial expansive pressures of coated and covered stents.

II. METHODOLOGY

A. Bare type

Jedwab and Clerc [1] simplified a bare type stent as combination of open-coiled helical springs. Each wire of bare stent was regarded as a spring and the equations for open-coiled helical spring by Wahl [2] was employed for wire model (Fig. 1). We use wire model of Jedwab and Clerc [1] for bare stents and wires for coated and covered stents. In this section, we rearranged the equations for open-coiled helical spring used in the study of Jedwab and Clerc [1].

A load is applied to elongate a stent in longitudinal direction. The load acting on the stent modeled with combination of n wires can be expressed as a function of pitch angle as in the following equation:

$$F_{wire} = 2n\left[\frac{GI_p \cos\beta}{K_3}\left(\frac{2\sin\beta}{K_3} - K_1\right) - \frac{EI\tan\beta}{K_3}\left(\frac{2\cos\beta}{K_3} - K_2\right)\right] \quad (1)$$

where K_1, K_2, K_3 are constants given by

$$K_1 = \frac{\sin 2\beta_0}{D_0},\ K_2 = \frac{2\cos^2\beta_0}{D_0},\ K_3 = \frac{D_0}{\cos\beta_0} \quad (2)$$

and β is pitch angle, I moment of inertia, I_p polar moment of inertia, E Young's modulus, G shear modulus, and n number of wires of a stent.

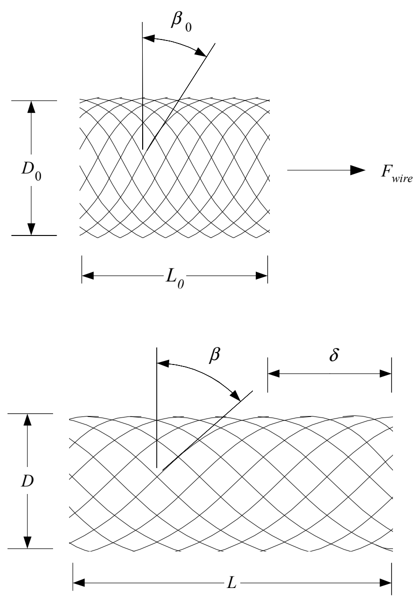

Fig. 1 Stent extension by longitudinal load F_{wire}.

Then, the radial expansive pressure of a stent is

$$P_{wire} = \frac{2F_{wire}c}{DL\tan\beta} \quad (3)$$

B. Coated type

A coated stent exerts two types of forces against radial compression: the spring restoring force (F_{wire}) exerted by metal wires and polymer knot force (F_{coat}) derived from the moments by the knots of polymer coating. The helical spring model [1] is employed to calculate wire spring force in this type of stent. The polymer knots are considered as torsional springs and the spring moments are calculated.

Fig. 2 shows stent in initial state and compressed state in θ-z plane (cylindrical coordination). When stent is compressed in radial direction as shown in Fig. 2(D), the moment from compressed torsional springs at each knots are exerted on wires of stent. The moment by one knot (M_{knot}) is

$$M_{knot} = k_{knot}(\beta - \beta_0) \quad (4)$$

where k_{knot} is a torsional spring constant. The moment exerted on one wire becomes

$$M_{wire} = k_{knot}(\beta - \beta_0) \times KNOTS_{wire} \quad (5)$$

where $KNOTS_{wire}$ is the number of knots in the wire. Thus, polymer knot force of a stent (F_{coat}) can be expressed as

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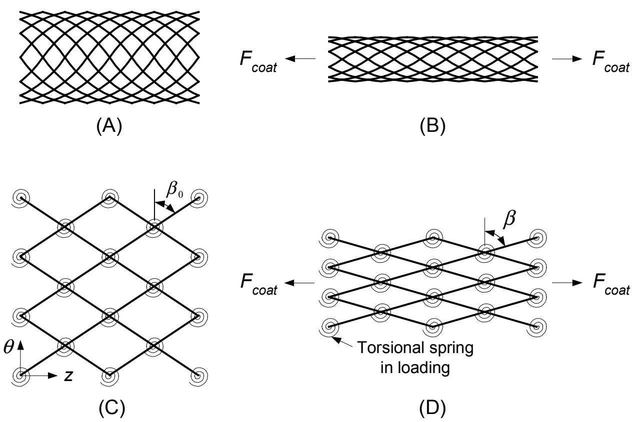

Fig. 2 Torsional spring model of coated stent: initial state (A), (C); compressed state (B), (D); unfolded view on θ-z plane (C), (D).

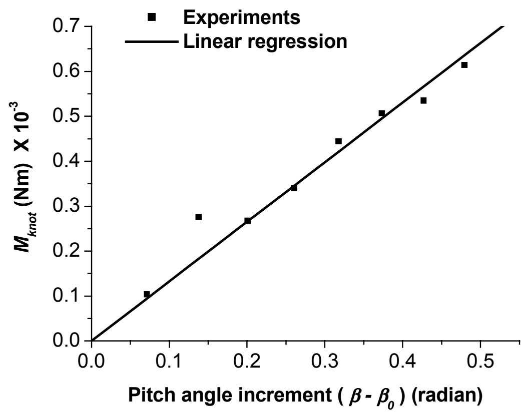

Fig. 3 The torsional spring constant k_{knot} is the slope of the linear regression curve: k_{knot} = 0.00133 (Nm/rad), R-Square=0.96712, p<0.0001.

$$F_{coat} = \frac{nM_{wire}}{L_{wire}\cos\beta} \tag{6}$$

The method to determine the torsional spring constant of the polymer coating will be described in the following. When the radial expansive pressures for both bare type and coated type stents are measured, the difference in their expansive pressures is caused by the torsional springs at knots (P_{coat}) only. That is,

$$P_{coat} = P_{coated\ stent} - P_{bare\ stent} \tag{7}$$

With known P_{coat}, D, β, and L, we can obtain polymer knot force F_{coat} of a stent:

$$F_{coat} = \frac{P_{coat}DL\tan\beta}{2c} \tag{8}$$

Then, the total moment M_{wire} exerting on the knots of a wire is expressed as

$$M_{wire} = \frac{L_{wire}F_{coat}\cos\beta}{n} \tag{9}$$

Applying linear regression to the M_{wire} from (5) and (9), the torsional spring constant k_{knot} can be obtained. Fig. 3 shows a regression result for a commercial stent, where the k_{knot} was 0.00133 (Nm/rad).

Given the longitudinal forces from wire and knots (F_{wire}, F_{coat}), number of spring turns (c), diameter (D), length (L), and pitch angle (β) of a compressed stent, one can calculate the radial expansive pressure of coated stent by the following equation:

$$P_{coated\ stent} = \frac{2(F_{wire}+F_{coat})c}{DL\tan\beta} \tag{10}$$

C. Covered stent

A covered stent exerts the force by the cover membrane itself and two more forces similar to coated stent. The membrane can be regarded as tensile springs and thus the covered stent is modeled as a combination of the following three elements: open-coiled helical springs, torsional springs, and tensile springs.

When stent is compressed, it elongates in its longitudinal direction. Consider the deformation of parallelogram cell as shown in Fig. 4(A). When the points A, B, and C are parallel to longitudinal axis of the stent, the longitudinal extension between the points A and B is

$$\delta_{AB} = \frac{2kl_{wire}(\sin\beta - \sin\beta_0)}{N} \tag{11}$$

Similarly, the extensions between B and C is

$$\delta_{BC} = \frac{2(N-k)l_{wire}(\sin\beta - \sin\beta_0)}{N} \tag{12}$$

Then, the total extension between the points A and C (δ_{AC}) is

$$\delta_{AC} = \delta_{AB} + \delta_{BC} = 2l_{wire}(\sin\beta - \sin\beta_0) \tag{13}$$

where l_{wire} is the length of wire of a cell. As shown in (13), δ_{AC} is independent of its location and the cell maintains a parallelogram shape during compression.

The length between A and B of uncompressed stent is

$$L_{AB} = \frac{2kl_{wire}\sin\beta_0}{N} \tag{14}$$

Combination of (11) and (14) yields

$$\frac{\delta_{AB}}{L_{AB}} = \frac{\sin\beta - \sin\beta_0}{\sin\beta_0} \tag{15}$$

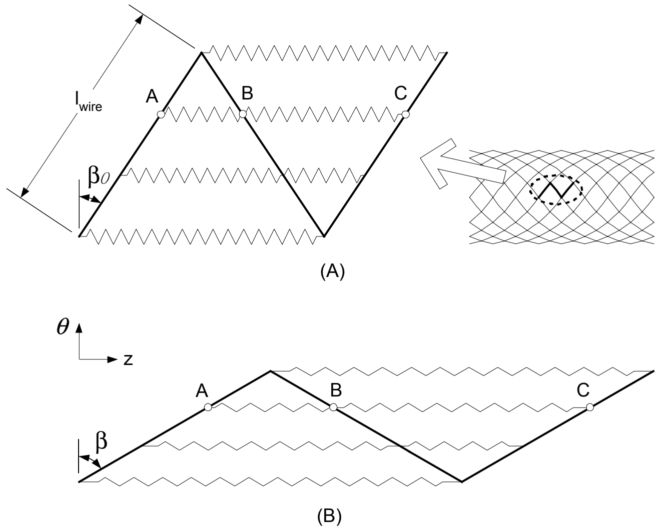

Fig. 4 Cover model of covered stent: initial state (A); compressed state (B).

Similarly, the strain between B and C is same as (15). Therefore, it is concluded that the strain (δ/L) is uniform and independent of its location on the stent.

If the cover membrane is assumed to be uniform in material and thickness, the tensile force of the polymer cover is

$$F_{cover} = \frac{AE}{L}\delta \tag{16}$$

where A is cross-sectional area and E is Young's modulus.

The expansive pressure P_{cover} due to the tensile force of cover membrane is then calculated as

$$P_{cover} = \frac{2F_{cover}c}{DL\tan\beta} \tag{17}$$

Unlike metals, the stress-strain curve of polymers does not demonstrate any linear portion even on initial tension. Thus, constant Young's modulus could not be used. In order to precisely determine the mechanical behavior of the polymer membrane, tensile test was performed and the resulting nonlinear stress-strain curve was employed to calculate the cover membrane tensile force. As shown in Fig. 5, the expansive pressure due to cover membrane demonstrates rapid increase during the initial phase of compression followed by insignificant change in pressure. Therefore, we can conclude that the cover membrane behaves as initial offset in total expansive pressure.

The actual amount of coating on wires of covered stent is not same as that of coated stent. In order to take into account this difference, the empirical coefficient α is employed, such that,

$$P_{covered\ stent} = P_{wire} + P_{cover} + \alpha P_{coat} \tag{18}$$

Thus, $P_{covered\ stent}$ is equal to

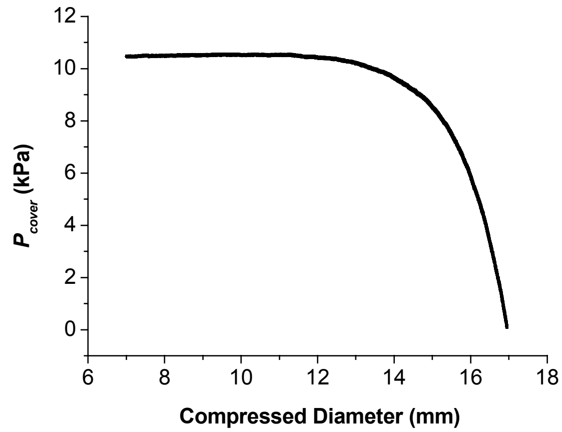

Fig. 5 P_{cover} versus compressed diameter of polyurethane covered stent.

$$P_{covered\ stent} = \frac{2(F_{wire} + F_{cover} + \alpha F_{coat})c}{DL\tan\beta} \tag{19}$$

III. RESULTS

A. Bare type

Fig. 6 shows the plot of both simulation and experimental results for bare type stent. Circles represent actual measurements conducted by Moon et. al [3] and solid line is calculated with the model (3). We can see the model is well matched to the experimental data.

B. Coated type

Fig. 7 shows the plot of simulation and experimental results for coated type stent. The model is well matched to the experimental data. Also, P_{bare} is about two to three times bigger than P_{coat}. That is, the force due to coating is dominant in coated type stent.

C. Covered type

Fig. 8 shows the plot of simulation and experimental results for covered type stent. The coefficient α was 0.5. The expansive pressure increases rapidly during the initial phase of compression region (0-10%) and increases slowly during the rest of compression (more than 10%). Similarly shown in Fig. 5, the nonlinear increase in expansive pressure is due to the expansion characteristics of polyurethane cover on the peripheral surface of stent.

D. Commercial stent

Similar characteristics of rapid increase in expansive pressure during the initial phase of compression were also observed in various commercially available covered type stents.

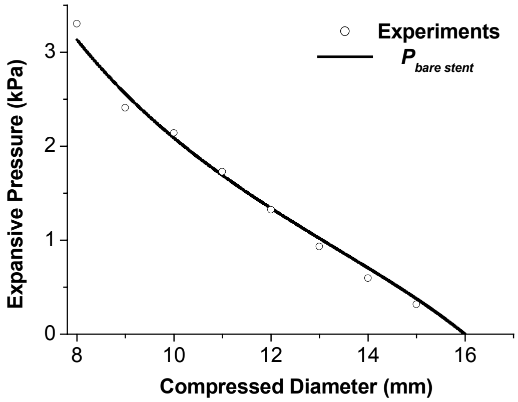

Fig. 6 Expansive pressure-deformation curve for bare type stent.

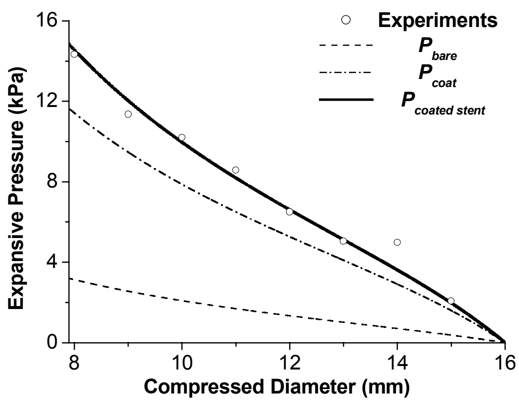

Fig. 7 Expansive pressure-deformation curves and experimental results for coated stent.

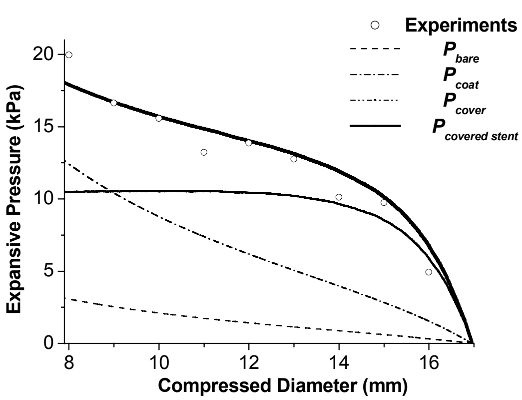

Fig. 8 Expansive pressure of prototype covered stent: Pwire , Pcoat ,and Pcover denote expansive pressures produced by wires, knot springs, and polyurethane cover, respectively.

For instance, the stents covered Y2P SR and Y3E SR that have polymer covers show rapid increase in expansive pressure while others do not in Fig. 9.

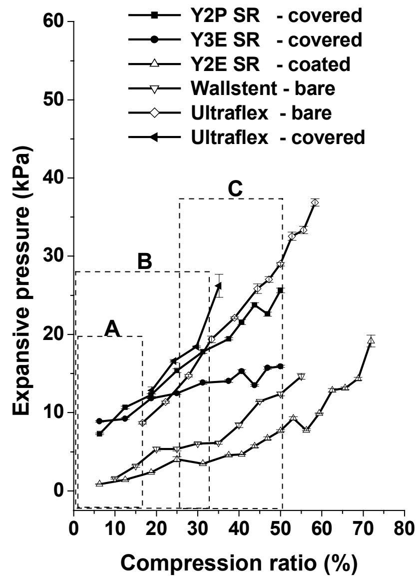

Fig. 9 Expansive pressure–deformation curves. Expansion pressure values were plotted as a function of compression ratio. Compression ratio is defined as the decrease in diameter divided by the initial diameter. Each point represents a mean of 5 separate determinations+/- SE.

IV. DISCUSSION

Physical properties of metal wire, polymer knots, and cover membrane are all elements in determining expansive pressure characteristics. Given these properties, the models presented in the present study allow accurate prediction on expansive pressure. Further, physical variables can be conveniently altered to design and manufacture stents with desired expansion characteristics.

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